UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler, District Court Judge

Honorable Karen M. Williams, Magistrate Judge

Honorable Thomas Vanaskie (Ret.), Special Discovery Master

MEMORANDUM OF LAW IN SUPPORT OF THE ZHP PARTIES'
OBJECTION TO SPECIAL MASTER ORDER NO. 28
DENYING A PROTECTIVE ORDER PRECLUDING THE
DEPOSITION OF BAOHUA CHEN

TABLE OF CONTENTS

			rage
I.	PRELIMINARY STATEMENT		
II.	PERTINENT FACTUAL BACKGROUND		
III.	PERTINENT PROCEDURAL BACKGROUND		
IV.	STANDARD OF REVIEW		8
V.	ARGUMENT		8
	A.	The Apex Doctrine Requires Actual, Not Speculative, "Unique Knowledge" to Rebut the Presumption Against Mr. Chen's Deposition	8
	B.	The Documents Referred to By Judge Vanaskie For Purposes of His Ruling Do Not Reveal Any Unique Knowledge By Mr. Chen That Would Rebut the Presumption Against Apex	
		Depositions	11
VI.	CONCLUSION		18

TABLE OF AUTHORITIES

Document 1386-1 PageID: 32521

Federal Cases

Ciarrocchi v. Unum Grp., No. CV 08-1704, 2009 WL 10676631 (D.N.J. Aug. 27, 2009)	11
In re Ex Parte Application of Jommi, 2013 WL 6058201 (N.D. Cal. Nov. 15, 2013)	3
George v. Penn. Tpk. Comm'n, No. 1:18-CV-766, 2020 WL 2745724 (M.D. Pa. May 27, 2020)	9
Reif v. CNA, 248 F.R.D. 448 (E.D. Pa. 2008)	11
Sturgeon v. Pharmerica Corp., 438 F. Supp. 3d 246 (E.D. Pa. 2020)	3
<i>United States ex rel. Galmines v. Novartis Pharms. Corp.</i> , C.A. No. 06-3213, 2015 WL 4973626 (E.D. Pa. Aug. 20, 2015) (Pratter, J.)	9, 17
Valeant Pharms. Int'l, Inc. v. AIG Ins. Co. of Canada, C.A. No. 18-493 (MAS)(LHG), 2020 WL 7768405 (D.N.J. Dec. 30, 2020)	8
Vanderklok v. United States, 868 F.3d 189 (3d Cir. 2017)	3
Younes v. 7-Eleven, Inc., C.A. No. 13-3500 (RMB/JS), 2015 WL 12844446 (D.N.J. Aug. 19, 2015)	1, 17
Federal Rules	
Fed. R. Civ. P. 26(c)	8, 9
Fed. R. Civ. P. 53(f)(3)-(4)	8
Non-Periodical Publications	
About Congress, The National People's Congress of the People's Republic of China, http://www.npc.gov.cn/englishnpc/c2842/column.shtml	3
National People's Congress, The National People's Congress of The People's Republic of China, http://www.npc.gov.cn/englishnpc/c2846/column2.shtml	2

I.

Document 1386-1 PageID: 32522

PRELIMINARY STATEMENT

Courts in the Third Circuit follow the apex deposition doctrine. Under that doctrine, the deposition of the highest-level executive is generally prohibited unless a specific showing is made that the executive in fact possesses unique information that has not or cannot be discovered from lower-level employees. In denying the ZHP Parties' motion to preclude on that basis the deposition of ZHP's President, Baohua Chen, Special Discovery Master Judge Vanaskie did not base his ruling on the identification of what, if any, unique information Mr. Chen possesses that could not be obtained, or was not in fact already obtained, from lower level employees as required under the apex doctrine. Instead, Judge Vanaskie ruled only that Mr. Chen "may" have some unspecified information that could be obtained at a deposition that would justify an exception to the apex doctrine. However, as applied in the Third Circuit, the apex doctrine requires more than a mere assumption about what the highest-level executive might know given his position. The apex doctrine requires an actual showing that the witness has unique knowledge about material issues. Plaintiffs have made no such showing here.

Furthermore, none of the documents on which Judge Vanaskie appeared to rely in denying the ZHP Parties' Motion—references to just six pages in five documents—actually identifies any unique knowledge on Mr. Chen's part as is

PageID: 32523

Document 1386-1

required to rebut the presumption against such apex depositions. Instead, those documents, as apparently relied on by Judge Vanaskie, in fact reveal only Mr. Chen's title and position, which Mr. Chen has held since the company's inception in 1989, that he studied chemical analysis in college from 1979 to 1983, and certain high-level communications that are typical of a corporate president. On the other hand, the record here clearly demonstrates that Plaintiffs sought, and in fact obtained, a mountain of discovery as to all relevant subjects (including testimony from the ZHP Parties on all 59 of the 30(b)(6) topics identified by Plaintiffs from ten corporate representatives and seven other fact witnesses and, in total, more than 350,000 produced documents), without any need for Mr. Chen's deposition.

For these reasons, the ZHP Parties respectfully request that the Court vacate Special Master Order 28 (Dkt. 1330) ("SMO 28"), and grant the ZHP Parties' motion for protective order to preclude the deposition of Mr. Chen.

PERTINENT FACTUAL BACKGROUND II.

Mr. Chen is the president of ZHP, a global company with 41 subsidiaries **ZHP** approximately 7,000 employees worldwide. companies and The

¹ In addition to his responsibilities as the president of ZHP, Mr. Chen holds a number of positions as a deputy elected to the National People's Congress of the People's Republic of China, the highest organ of State power in China. See Dkt. 1244 at 6; Dkt. 1244-10 (chart identifying Mr. Chen's roles as a Congressman in the Chinese government); see also National People's Congress, THE NATIONAL PEOPLE'S CONGRESS PEOPLE'S OF THE REPUBLIC OF CHINA. http://www.npc.gov.cn/englishnpc/c2846/column2.shtml (last visited July 13.

Document 1386-1 PageID: 32524

commercially produce more than 50 drug molecules (not merely the one at issue in this case). As per Plaintiffs, this case concerns nitrosamine impurities that purportedly resulted in valsartan due to the introduction in 2011 of a solvent in the multi-step manufacturing process. As defined by Plaintiffs in their 30(b)(6) notice, their case as to the alleged nitrosamine impurities in the ZHP Parties' valsartan covers seven topics encompassing 59 different sub-topics:

- 1. Testing of Valsartan API;
- Quality Assurance and Quality Control Activities;
- 3. Process Development;
- 4. Communications with Regulatory Agencies;
- 5. ZHP's Communications with API and Finished Dose Customers and Downstream Customers;
- 6. Compliance with cGMPs; and
- 7. Product Tracing.

2021) and About Congress, THE NATIONAL PEOPLE'S CONGRESS OF THE PEOPLE'S REPUBLIC OF CHINA, http://www.npc.gov.cn/englishnpc/c2842/column.shtml (last visited on July 13, 2021) (describing National People's Congress and structure of the Chinese government). The Court can take judicial notice of these websites. See Vanderklok v. United States, 868 F.3d 189, 205 (3d Cir. 2017) (citing Daniels-Hall v. Nat'l Educ. Ass'n, 629 F.3d 992, 998 (9th Cir. 2010)) (taking judicial notice of information "publicly available on government websites"); Sturgeon v. Pharmerica Corp., 438 F. Supp. 3d 246, 259 (E.D. Pa. 2020) ("[I]nformation found on government websites is widely considered both self-authenticating and subject to judicial notice."); In re Ex Parte Application of Jommi, 2013 WL 6058201, at *2 (N.D. Cal. Nov. 15, 2013) ("A court may take judicial notice of public records of governmental entities and authoritative sources of foreign law, including information posted on government websites[.]").

Document 1386-1 PageID: 32525

<u>Dkt. 651-1</u> at Ex. F.

The ZHP Parties produced ten 30(b)(6) witnesses on the above topics,² resulting in thousands of pages of deposition testimony, including the witnesses with most knowledge about and responsibility for the seven topics identified by Plaintiffs. Specifically, over the course of the depositions, (1) "Testing of Valsartan API" was testified to by the heads of ZHP's analytical operations, analysis, quality assurance, and quality control departments; (2) "Quality Assurance and Quality Control Activities" was testified to by the heads of ZHP's quality assurance and quality control departments; (3) "Process Development" was testified to by the head of ZHP's technology department and the President of ZHP's research and development subsidiary; (4) "Communications with Regulatory Agencies" was testified to by the heads of the regulatory affairs departments at ZHP and Prinston; (5) "ZHP's Communications with API and Finished Dose Customers and Downstream Customers" was testified to by the head of ZHP's API sales department and the head of Solco's finished dose sales department, and the heads of ZHP's quality assurance and quality control departments; (6) "Compliance with cGMPs" was testified to by the heads of ZHP's quality assurance and quality control departments; and (7) "Product Tracing" was

² All of the 30(b)(6) witnesses were also deposed as fact witnesses.

Document 1386-1 Filed 07/13/21

PageID: 32526

testified to by the head of ZHP's API sales department and the head of Solco's finished dose sales department.³ *See* Dkt. 703-1.

Plaintiffs have also issued to the ZHP Parties more than 120 document requests, in response to which the ZHP Parties have produced more than 350,000 documents in response to the topics Plaintiffs deemed important from the 83 ZHP Party custodians for which Plaintiffs requested, using the more than 400 search terms to which Plaintiffs agreed.

III. PERTINENT PROCEDURAL BACKGROUND

Plaintiffs first sought Mr. Chen's deposition in December 2020. Dkt. 684 at 3-7. Given what was even then seen as the clear potential applicability of the apex doctrine, it was significant that Judge Schneider ruled that while Mr. Chen's deposition could be tentatively scheduled, it should not be conducted, if at all, until "after a sufficient deposition record is developed," and Judge Schneider "granted [ZHP] leave to file a Motion for Protective Order to quash Mr. Chen's deposition." Dkt. 704.

³ In addition to the ten 30(b)(6) depositions, Plaintiffs also deposed another seven ZHP Party witnesses in their individual capacities. Through those witnesses, Plaintiffs received further testimony on communications with API customers and API marketing; finished dose quality assurance activities and API quality assurance activities; valsartan research and process development; and detailed information regarding ZHP's U.S. subsidiaries from Jun Du, the Vice Chairman at ZHP and CEO of ZHP's U.S. subsidiaries, Solco, Huahai U.S., Inc., and Prinston.

Accordingly, and as was envisioned by Judge Schneider, the ZHP Parties did in fact ultimately file, on May 17, 2021, a Motion for Protective Order to preclude

the deposition of Mr. Chen (Dkt. 1247), after some 13 ZHP Party witnesses had

Document 1386-1

PageID: 32527

already been deposed.4

In support of their Motion, the ZHP Parties pointed to a wide range of deposition testimony already secured by Plaintiffs. That discovery establishes that Mr. Chen does not possess unique knowledge as to the relevant issues in this case that could not be obtained, and which in fact had already been obtained, from the many other ZHP Party witnesses and/or from the ZHP Parties' extensive production of more than 350,000 documents. See Dkt. 1247 at 17-29; Dkt. 1295 at

Plaintiffs opposed the ZHP Parties' motion, arguing that any "purported 'apex doctrine' does not apply to Mr. Chen." Dkt. 1298 at 23-25. Plaintiffs argued that they should be permitted to depose Mr. Chen because of what Plaintiffs claimed was Mr. Chen's "unique position within the ZHP Organization where everyone reports to him" and because he purportedly led ZHP's departments and subsidiaries to "develop, manufacture, sell, and recall" valsartan. Dkt. 1298 at 1, 21-23.

3-12.

⁴ With Judge Vanaskie's permission, the ZHP Parties supplemented their motion on June 3, 2021, to incorporate testimony from the four remaining ZHP Party depositions. Dkt. 1295 (supplemental motion).

In response, the ZHP Parties cited authority demonstrating that, contrary to Plaintiffs' assertion, the Third Circuit indeed follows the apex doctrine and, most significantly, that Plaintiffs had not rebutted the apex doctrine's presumption by demonstrating that Mr. Chen actually had any unique knowledge that would support an exception to the apex doctrine as applied in this Circuit. Dkt. 1307 at 3-14.

This notwithstanding, on June 21, 2021, Judge Vanaskie denied the ZHP Parties' Motion, finding that Mr. Chen "may have unique knowledge that [Plaintiffs] have been unable to obtain from the numerous witnesses deposed thus far." SMO 28 at 8 (emphasis added). In reaching that conclusion, Judge Vanaskie appeared to rely on six pages from five documents, as follows:

- ZHP01662344 and ZHP01662359 (Pages within Same Document)

 a description of personnel and an organizational chart.
- **SOLCO0012089**⁵ an email chain discussing an update to Mr. Chen on sales figures.
- **PRINSTON00162373** the 2018 Chuannan FDA Establishment Inspection Report.
- **PRINSTON00083647** an FDA inspection report.

⁵ Special Master Order No. 28 inadvertently misidentifies the bates number for this document as SOLCO00189499. Exhibit O to Plaintiffs' Opposition was numbered SOLCO0012088-90, and SOLCO0012089 contains the language quoted in the parenthetical for those documents in the Order.

• **ZHP01423197** – a draft communication to the European Directorate for the Quality of Medicines.

As discussed herein, that which was identified as a purported basis for making an exception under the apex doctrine actually falls far short of what the cases require for such an exception to be made.

IV. STANDARD OF REVIEW

A special master's conclusions of law and findings of fact are reviewed *de novo*. Fed. R. Civ. P. 53(f)(3)-(4). For example, where a special master's order interprets cases and applies them to rule whether certain discovery must be produced, a special master makes "legal determinations that are subject to *de novo* review." *Valeant Pharms. Int'l, Inc. v. AIG Ins. Co. of Canada*, C.A. No. 18-493 (MAS)(LHG), 2020 WL 7768405, at *4 (D.N.J. Dec. 30, 2020). Thus, Judge Vanaskie's determination that the apex deposition doctrine does not preclude Mr. Chen's deposition, <u>SMO 28</u> at 8, should be reviewed *de novo. See id*.

V. <u>ARGUMENT</u>

A. The Apex Doctrine Requires Actual, Not Speculative, "Unique Knowledge" to Rebut the Presumption Against Mr. Chen's Deposition

It is black-letter law that this Court may for good cause issue an order protecting a person from the undue burden of a deposition. Fed. R. Civ. P. 26(c)(1). Where that person is at the "apex" of a corporation, his or her deposition

is presumed to be unduly burdensome⁶—and thus precluded under Rule 26(c)—unless its proponent can specifically show, and with real substance, that the apex witness *has* unique knowledge that could not be obtained from a less burdensome source. *See United States ex rel. Galmines v. Novartis Pharms. Corp.*, C.A. No. 06-3213, 2015 WL 4973626, *2 (E.D. Pa. Aug. 20, 2015) (Pratter, J.) ("The apex doctrine . . . appl[ies] a rebuttable presumption that a high-level official's deposition represents a significant burden upon the deponent."); *George v. Penn. Tpk. Comm'n*, No. 1:18-CV-766, 2020 WL 2745724, at *3 (M.D. Pa. May 27, 2020) (denying motion to compel apex deposition, notwithstanding fact that the apex witness participated in events at issue, because "it cannot be said that he possessed superior, or unique knowledge of these events") (emphasis added).

This standard not withstanding, Judge Vanaskie denied the ZHP Parties' motion for protective order, ruling only that Mr. Chen "may have unique

⁶ In addition to the burdens faced by all apex witnesses, Mr. Chen is a Chinese citizen who resides in China and does not speak or read English. Chinese law prohibits the depositions of Chinese citizens in U.S. legal proceedings in China. Consequently, were he granted a travel permit by the Chinese government to be deposed, Mr. Chen would need to travel to Macau or another country to be deposed in this action, and a normal 7-hour deposition would be extended to 12.25 hours to allow for an interpreter to translate every question and answer. Thus, a deposition of Mr. Chen would actually occur over two 5-hour and one 2.25 hour sessions of testimony, requiring Mr. Chen to be occupied by his deposition for the better part of an entire work week. Counsel for ZHP has been advised by ZHP that at this time the Chinese government has not issued a travel permit for Mr. Chen to leave China to be deposed in this action.

PageID: 32531

knowledge." SMO 28 at 8 (emphasis added). Judge Vanaskie's ruling contravenes applicable Third Circuit precedent, which precludes apex depositions absent a specific showing by the party seeking the deposition that the witness actually has unique knowledge. See Younes v. 7-Eleven, Inc., C.A. No. 13-3500 (RMB/JS), 2015 WL 12844446, at *2 (D.N.J. Aug. 19, 2015) (precluding apex deposition where "plaintiffs have not shown that Rebelez and DePinto have personal and unique knowledge and that the information plaintiffs want cannot be obtained from other witnesses" (emphasis added)). In Younes, as here, the plaintiffs had the opportunity to seek the information sought from the apex witness from multiple lower-level witnesses, and did not establish that the apex witness actually possessed unique knowledge.

Plaintiffs have taken and/or participated in a substantial number of present responsible and former depositions of 7-Eleven employees. Thus, plaintiffs have had more than a fair opportunity to obtain in discovery the information they reasonably needed to prove their claims and defenses. The record does not show that [the apex witnesses] have any unique or personal knowledge that has not already been revealed in the mountain of discovery taken in the case. The record also does not show that the information plaintiffs now want to question [the apex witnesses] about could not have been obtained from lower level employees.

Id. at *2 (emphasis added). The Court there precluded the deposition of the company's highest-ranking officer. The same standard should have been applied here. In fact, this principle should apply here with extra force because Plaintiffs did not make a showing that they had not already secured the information in question Document 1386-1 PageID: 32532

from their very extensive discovery of many other ZHP Party witnesses, including ten 30(b)(6) depositions.

Thus, in all events, the mere allegation that there is a possibility that the apex witness *may* have such information is as a matter of law insufficient to rebut the presumption against apex depositions. *Id.*; *see also Reif v. CNA*, 248 F.R.D. 448, 454 (E.D. Pa. 2008) (precluding apex deposition where the party had not shown "Lilenthal *possessed* any special or personal unique knowledge of the Reifs' termination or how his 2002 statement influenced their termination or tenure at CNA Financial Corp" (emphasis added)); *Ciarrocchi v. Unum Grp.*, No. CV 08-1704 (JBS/AMD), 2009 WL 10676631, at *3 (D.N.J. Aug. 27, 2009) (prohibiting apex deposition because plaintiff failed to show that witness had unique knowledge).

B. The Documents Referred to By Judge Vanaskie For Purposes of His Ruling Do Not Reveal Any Unique Knowledge By Mr. Chen That Would Rebut the Presumption Against Apex Depositions

To say the very least, this is hardly a case in which an exception to the apex doctrine is appropriate because the inquiring party has not otherwise secured sufficient discovery on the topics it has deemed important. In fact, here just the opposite is true. After review of more than 350,000 documents and taking the depositions of 17 ZHP Party witnesses on all of the topics Plaintiffs deemed important, Plaintiffs still could not identify a sole unique fact possessed by Mr.

Document 1386-1 PageID: 32533

Chen that they could not have obtained (or did not already obtain) from the mountain of discovery already in their possession. This is not surprising. One would not expect that the head of a company of approximately 7,000 employees with a global pharmaceutical portfolio would have unique personal knowledge about details not possessed by the employees deputized to have such knowledge.

Judge Vanaskie did not identify any such facts, either. In denying the ZHP Parties' Motion to preclude the deposition of Mr. Chen, Judge Vanaskie made reference to only six pages within five documents identified by Plaintiffs. But none of those documents enables Plaintiffs to make the showing required of them—that there is any unique information possessed by Mr. Chen that could not be obtained from lower-level employees, if not, as is the case here, already obtained from such other employees.

ZHP01662344 and ZHP01662359, found within the same document, simply show information regarding ZHP personnel and organizational charts. The document identifies Mr. Chen at the top of the organizational chart and states that he trained as a chemical engineer and generally "has wide experience in the

⁷ That Judge Vanaskie cited only five documents out of the more than 350,000 the ZHP Parties produced is telling as to Mr. Chen's lack of involvement with the material issues in this case. The 350,000 documents included the custodial files of 83 custodians. While Mr. Chen was not among those custodians, to the extent he had communicated with any of those custodians on relevant topics, those emails would have been produced and Plaintiffs could have asked deposition questions about them (and cited them to Judge Vanaskie).

product development and quality management of bulk drugs." It is, of course, hardly surprising that the founder and president of a company would be located at the top of an "org chart" or have a background in what his company does. But certainly such a document does not establish that Mr. Chen has any *unique* knowledge regarding the particular issues relevant to this case. It is not an overstatement to say that if this document is sufficient to enable an apex deposition, then no apex deposition could ever be precluded.

SOLCO0012089 is an email chain among several ZHP and Solco executives (including Hai Wang and Jun Du, who were both deposed by Plaintiffs) regarding ZHP's challenges in marketing and business development for valsartan. A Solco executive notes that (based on the same information provided to Hai Wang and Jun Du in the email chain) Mr. Chen wished to expand ZHP's market share. Plaintiffs point to nothing in these emails that demonstrates Mr. Chen's unique knowledge of ZHP's market share or pricing of valsartan, as such market share or pricing pertain, if at all, to the alleged nitrosamine impurities at issue here. Nor does the fact that a company's chief executive asked about the company's performance satisfy the apex deposition doctrine's requirement for actual unique

⁸ Plaintiffs cannot reasonably allege that Mr. Chen's testimony as to the interrelationship between the various ZHP entities would be unique given that Plaintiffs have already deposed Jun Du, Eric Gu, Eric Tsai, Hai Wang, and Xiaodi Guo, all of whom also hold senior positions in multiple ZHP Party entities, on this subject. *See* Dkt. 1247 at 4-5, 11, 17-20; Dkt. 1307 at 2-3, 5-6.

Case 1:19-md-02875-RMB-SAK

PageID: 32535

information. Again, being interested in the company's performance is something presumably shared by all chief executives. Moreover, Plaintiffs have already obtained 30(b)(6) testimony from the head of ZHP's API sales department and the president of Solco (which sells ZHP finished dose) regarding sales and profits for ZHP's valsartan API and Solco's finished dose products (manufactured by ZHP), respectively, and deposed Jun Du (ZHP's Vice Chairman) regarding ZHP's business development strategies.

PRINSTON00162373 does not even address communications by Mr. Chen. Instead, at most this document, written by an FDA inspector, merely paraphrases statements purportedly made to the FDA by Jun Du to the effect that the valsartan manufacturing process change was made in order to increase world market share. Plaintiffs already deposed Mr. Du, and had many opportunities to ask, and did ask, Mr. Du about this specific statement, as set forth in this specific document. Therefore, Plaintiffs have already obtained the best evidence of the circumstances involving this information. There is nothing Mr. Chen could possibly add to Mr. Du's testimony that would not be duplicative of Mr. Du's prior testimony.

PRINSTON00083647 is an FDA inspection report that merely states Mr. Chen is the President/Chairman of ZHP, and has "ultimate authority at the firm and takes full responsibility for the company's operations." This is a truism for all presidents/CEOs. This document only confirms that Mr. Chen is in fact the classic

apex witness—not that he has any knowledge—much less unique knowledge regarding ZHP's interactions with the FDA. Nor does the document identify any specific role played by Mr. Chen in creating and implementing corrective actions in response to the FDA's 483 letter. See also Dkt. 1247-13 at ¶ 10 (Declaration of Linda Lin). These roles related to other senior employees of ZHP, including Jucai Ge and Minli Zhang (already deposed by Plaintiffs), and Jun Du (also already deposed), who "was present every day of the inspection," and assumed all responsibility. Mr. Chen, by contrast, was only present for the opening and closing meetings of this FDA inspection as a matter of formal protocol, see Dkt. 1247-13 at ¶ 9, while other 30(b)(6) witnesses deposed by Plaintiffs participated far more meaningfully in the inspection.⁹ Moreover, Mr. Du, and not Mr. Chen, was the highest-ranking official in attendance at the FDA inspection in July 2018 regarding the nitrosamine impurities at issue, see PRINSTON00162349 at ¶ 3 ("On July 23, 2018 at Zhejiang Huahai Pharmaceutical Co., Ltd., Mr. Hustedt and I showed our credentials to Mr. Jun Du, Executive Vice President. Mr. Du stated he is the most

⁹ Plaintiffs have subjected senior ZHP Party officers to dozens of hours of depositions regarding FDA inspections and communications, including Linda Lin (the head of ZHP's Regulatory Affairs Department), Min Li, Xiaodi Guo, Minli Zhang, Eric Tsai, Jucai Ge, Qiangming Li, Peng Dong, Jie Wang and Remonda Gergis, as well as Jun Du, who was specifically appointed to facilitate certain FDA inspections. *See* Dkt. 1247 at 6-12, 20-23; Dkt. 1307 at 2-4, 6-8. These witnesses were consistent participants in FDA inspections and communications, whereas Mr. Chen only played a limited role. *Id*.

responsible person at the facility"), and Mr. Du was questioned extensively about this inspection and his related communications with the FDA. Mr. Chen has no unique knowledge of this FDA inspection or any other inspections that other witnesses could not have provided to Plaintiffs, and already have.

ZHP01423197 is a merely a draft letter from ZHP to the European Directorate for the Quality of Medicines that provides a high-level summary of ZHP's investigational work related to valsartan. While purportedly written on behalf of Mr. Chen, the metadata makes clear the draft is from the custodial file of and authored by Linda Lin, ZHP's head of Regulatory Affairs, whom Plaintiffs have already deposed. Further, the draft provides high-level, general information and shows only that employees of ZHP drafted a communication to a regulatory body. It does not show any action on Mr. Chen's part with respect to regulatory communications, let alone his having any unique knowledge about the facts at issue. As two other 30(b)(6) witnesses were designated to testify about the ZHP Parties' communications with regulatory authorities, any such testimony from Mr. Chen on this point would only be duplicative. See Dkt. 703-1.

Taken together, or individually, these five documents do not identify any unique information actually possessed by Mr. Chen that Plaintiffs could not have obtained from any of the prior 17 ZHP Party witnesses. Certainly, documents merely stating Mr. Chen's title or that he studied chemical analysis in college more

than four decades ago are not evidence that Mr. Chen possesses unique knowledge about material facts undiscoverable or in fact already discovered from lower-level employees. See, e.g., United States ex rel. Galmines, 2015 WL 4973626, at *1-3. Instead, they show that Mr. Chen is not engaged in the "nuts and bolts" of ZHP's product manufacturing and quality assessment. Indeed, no fewer than five ZHP Party witnesses testified that Mr. Chen was not involved in any day-to-day activities relating to the manufacture of valsartan, nor did he coordinate or lead these efforts in any substantive way that would result in him having non-duplicative, unique knowledge that Plaintiffs could not have already obtained. See Dkt. 1247 at 17-29; Dkt. 1295 at 3-12; Dkt. 1307 at 9-14.

Further, here Plaintiffs' discovery from the ZHP parties consists of more than 350,000 documents produced and 17 witnesses deposed, resulting in more than 164 hours of testimony. Clearly, Plaintiffs have already created a substantial record as to all of the subjects Plaintiffs deem important as to the ZHP parties, including the ZHP Parties' interrelationships, the ZHP Parties' interactions with the FDA, and the manufacturing, sale, and recall of valsartan. *See* Dkt. 1247 at 17-29; Dkt. 1295 at 3-12; Dkt. 1307 at 9-14. Under the apex doctrine, the fact of this inarguable mountain of evidence argues strongly against requiring Mr. Chen's deposition. *Younes*, 2015 WL 12844446, at *2 (precluding apex deposition because

of "mountain of discovery taken in the case" and resultant lack of unique knowledge by apex witness).

VI. <u>CONCLUSION</u>

For all of the foregoing reasons, and those stated in the ZHP Parties' prior briefing on this issue, the ZHP Parties respectfully request that the Court vacate and reverse Special Master Order No. 28 and grant the Motion for Protective Order as to the deposition of Baohua Chen.

July 13, 2021

Respectfully submitted,

By: /s/ Seth A. Goldberg

DUANE MORRIS LLP Seth A. Goldberg 30 South 17th Street Philadelphia, Pennsylvania 19103 Tel.: (215) 979-1000 Fax: (215) 979-1020

SAGoldberg@duanemorris.com

Attorneys for Zhejiang Huahai Pharmaceutical Co, Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare US, LLC

DM1\12237366.3